BENZOYL PEROXIDE- benzoyl peroxide suspension Perrigo New York Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Perrigo Benzoyl Peroxide 10% Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

Use

for the treatment of acne

Warnings

For external use only

Do not use

if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if

irritation becomes severe

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- shake well
- Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- wet area to be cleansed
- apply acne wash and gently massage area for 1-2 minutes
- rinse thoroughly and pat dry
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Inactive ingredients

carbomer homopolymer, citric acid*, edetate disodium, glycerin, imidurea, lauryl methacrylate/glycol dimethacrylate crosspolymer, purified water, sodium C14-16 olefin sulfonate, sodium hydroxide *may contain this ingredient

Questions? 1-800-719-9260

Package/Label Principal Display Panel

Benzoyl Peroxide 10% Acne Medication Wash NET WT 8 OZ (227 g)

Perrigo[®]

NDC 45802-**318**-34

Benzoyl Peroxide 10%

Acne Medication Wash

NET WT 8 OZ (227g)



: 16334 RT F5

TOPICAL

Drug Facts

Store at 20-25°C (68-77°F)

Active ingredient Benzoyl peroxide 10%.....

Purpose Acne medication.

802

Use for the treatment of acne

Warnings For external use only

Do not use if you ■ have very sensitive skin ■ are sensitive to benzoyl peroxide

When using this product

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Stop use and ask a doctor if ■ irritation becomes severe

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

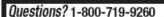
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Inactive ingredients carbomer homopolymer, citric acid*, edetate disodium, glycerin, imidurea, lauryl methacrylate/glycol dimethacrylate crosspolymer, purified water, sodium C14-16 olefin sulfonate, sodium hydroxide *may contain this ingredient

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Distributed By Perrigo, : 16334 RT B3



BENZOYL PEROXIDE

benzoyl peroxide suspension

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:45802-318

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII: W9 WZN9 A0 GM) | BENZOYL PEROXIDE | 10 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)				
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)				
GLYCERIN (UNII: PDC6A3C0OX)				
IMIDUREA (UNII: M629807ATL)				
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)				
WATER (UNII: 059QF0KO0R)				
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:45802-318-01	142 g in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013			
2	NDC:45802-318-34	227 g in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2013			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333D	02/20/2013			

Labeler - Perrigo New York Inc (078846912)

Revised: 1/2019 Perrigo New York Inc